IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

BRAIDWOOD MANAGEMENT, INC., *et al.*, Plaintiffs, v. XAVIER BECERRA, *et al.*, Defendants.	Civil Action No. 4:20-cv-00283-O

DECLARATION OF JEFF WU

I, Jeff Wu, pursuant to 28 U.S.C.§ 1746, and based upon my personal knowledge and information made known to me in the course of my employment, hereby make the following declaration with respect to the above-captioned matter:

1. I currently serve as the Deputy Director for Policy in the Center for Consumer Information & Insurance Oversight (CCIIO) at the Centers for Medicare & Medicaid Services (CMS). In my role as the Deputy Director, I oversee policy for the commercial health insurance market, including the Health Insurance Exchanges (exchanges).

2. On March 30, 2023, the United States District Court for the Northern District of Texas issued a decision in the case of *Braidwood Management Inc. v. Becerra*, 4:20-cv-00283-O, vacating any and all actions taken by the Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments) to implement or enforce the Affordable Care Act's preventive service coverage requirements in response to an "A" or "B" rating by the United States Preventive Services Task Force (USPSTF) on or after March 23, 2010, and

enjoining the Departments from implementing or enforcing the preventive service coverage requirements in response to an "A" or "B" rating from USPSTF in the future (the "*Braidwood* decision"). On March 31, 2023, the U.S. Department of Justice filed a notice of appeal.

3. More than 150 million people with private insurance currently can receive preventive services without cost-sharing under the ACA. *See* Access to Preventive Services without Cost-sharing: Evidence from the Affordable Care Act, Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, Issue Brief No. HP-2022-01 (January 2022), https://perma.cc/UH32-KX6D.

4. The *Braidwood* decision will likely lead to individuals losing access to services, either because their plans or issuers drop coverage of certain preventive services or because the plans or issuers impose cost sharing on such services, leading to individuals forgoing preventive care out of concern about paying for these services. Indeed, the *Braidwood* decision could generate enough confusion that consumers may be concerned they will face cost sharing even when they will not, which could further lead to a decrease in utilization of preventive services. These losses or changes in coverage may result in adverse health outcomes.

5. Most group health plans and group and individual market health insurance policies operate on a calendar year basis, but a significant minority operate on different cycles. For example, universities may offer health insurance policies tied to their academic years and local and state governments may offer group health plans using state fiscal years. Group health plans start in a variety of months throughout the year based on what makes sense for their coverage needs (for example, if a business launched in September, they likely would have started coverage in September and will continue starting their plan years in September moving forward).

6. Plans and issuers do not typically make changes to coverage or cost sharing mid-

year because they price their insurance premiums or premium contributions and design their health plans based on coverage for a full year, and issuers have signed contracts with enrollees and with employers stating that they will cover certain services at certain costs through the end of the plan year. However, certain mid-year changes might be permissible under these contracts, and at least some plans or issuers are expected either to drop coverage or impose cost sharing for certain preventive services because of the *Braidwood* decision. Because not all plans and policies operate on the calendar year cycle, and because certain mid-year changes might be permissible, some of this expected coverage loss could occur in the near future.

7. The *Braidwood* decision affects dozens of preventive services that were added or modified after March 23, 2010, including PrEP for people at high-risk of HIV, colorectal cancer screening for people ages 45-49, lung cancer screenings, and statins for adults at increased risk for cardiovascular disease, just to name a few.

8. Indeed, in light of the *Braidwood* decision, CMS expects that some employers will drop some of the more costly preventive services or impose cost sharing on such services. CMS also expects that some enrollees will choose to forgo preventive services due to plans or issuers imposing cost sharing on such services. For example, employers may decide to drop PrEP coverage (and related ancillary services) because it is a relatively expensive service to cover, it is a newer recommendation, and individuals eligible for PrEP may not be a risk profile that plans and issuers want to attract. It is also possible that some employers may decide to drop coverage of colonoscopies for adults age 45 to 49 due to the cost of such procedures.

9. A number of studies on the effects of cost sharing on health care services have shown a reduction in the use of services after cost sharing increased, regardless of income. *See* Kaiser Commission on Medicaid and the Uninsured, *Premiums and Cost-Sharing in Medicaid: A*

Review of Research Findings (2013), https://perma.cc/U5S6-74KP. More recent research on the effects of cost sharing on low-income individuals also found reductions in the use of health care services, and even small increases in cost sharing can create insurmountable financial barriers for people with low incomes. *See id.* at 6.

10. Research has also shown significant declines specifically in the utilization of preventive services after the introduction of or increase in cost sharing. *See id.* at 6-7. For example, one study analyzed the effect of cost sharing on mammogram utilization among Medicare beneficiaries, comparing the use of mammography services for individuals in plans that had increased or instituted new copays to individuals in plans that had not. *See id.* at 9. The results showed that biennial screening rates were 8.3 percentage points lower in cost sharing plans than in those with full coverage, and that the effect was magnified for women residing in lower income areas. *See id.* (citing Amal N. Trivedi et al., *Effect of Cost Sharing on Screening Mammography in Medicare Health Plans*, 358(4) NEW ENG. J. MED. 375, 375 (2008)); *see also id.* at 8-10 (compiling other studies showing a decrease in utilization of preventive services after the introduction of or increase in cost sharing).

11. In addition to studies demonstrating that cost sharing leads to a decrease in utilization of services, a recent poll indicates that a similar result can be expected here. The Morning Consult (a business intelligence company) polled a sample of 2,199 U.S. adults in January 2023 to better understand if preventive service utilization would be affected by the potential *Braidwood* decision. *See* Jay Asser, HealthLeaders, *Patients Likely to Skip Preventive Care if ACA Rulings Holds* (Mar. 17, 2023), https://perma.cc/RKS3-EXXM. At least two in five respondents said that cost sharing barriers would prevent them from obtaining most of the preventive services currently covered by the Affordable Care Act. *See id.*

12. A decrease in the utilization of preventive services is likely to lead to adverse health outcomes. For example, according to one recent study of men who have sex with men (MSM), for every 10% decrease in PrEP coverage resulting from the anticipated *Braidwood* decision (i.e. for every 10% decrease in PrEP-indicated MSM receiving PrEP), the authors estimate an additional 1,140 HIV infections in the following year in that population. *See* A. David Paltiel et al., *Increased HIV Transmissions With Reduced Insurance Coverage for HIV Preexposure Prophylaxis* (2023), https://perma.cc/ED2W-X7KL. The authors call this a "conservative" estimate, as they only considered primary HIV transmission effects in the year after the ruling, ignoring both infections occurring beyond one year and all secondary transmissions. *Id.* Additionally, PrEP is used by other populations and can help prevent maternal HIV infection and therefore the risk of transmitting HIV to a child through childbirth or breast feeding.

13. Younger people could also lose coverage for colorectal cancer screening, as the 2021 recommendation from USPSTF lowered the minimum age of screening from 50 to 45. Colorectal cancer is the third leading cause of cancer death in the nation with cases increasing in younger ages. *See* American Cancer Society, *Key Statistics for Colorectal Cancer* (2023), https://perma.cc/Y7G6-NPST. During a colonoscopy, physicians remove pre-cancerous polyps as they find them to avoid such polyps becoming cancerous in subsequent years. The American Cancer Society notes that "observational studies suggest that colonoscopy can help reduce [colorectal cancer] incidence by about 40% and mortality by about 60%." *See* American Cancer Society, *Colorectal Cancer: Facts and Figures 2020-2022* at 19, https://perma.cc/PFS2-6L64. The rate of people being diagnosed with colon or rectal cancer each year has dropped overall since the mid-1980s, mainly because more people are getting screened and changing their

lifestyle-related risk factors. *See supra*, *Key Statistics for Colorectal Cancer*, https://perma.cc/Y7G6-NPST.. From 2011 to 2019, colorectal cancer incidence rates dropped by about 1% each year, but this downward trend is mostly in older adults. *Id.* In people younger than 50, rates have been increasing by 1% to 2% a year since the mid-1990s. *Id.* These percentages are significant given the number of new cases each year—the American Cancer Society estimates that there will be 106,970 new cases of colon cancer and 46,050 new cases of rectal cancer in the United States in 2023. *See id.*

14. People could also lose coverage for lung cancer screening, as the USPSTF issued its initial recommendation for lung cancer screening in 2014, and then later expanded it. Lung cancer is the leading cause of cancer deaths among both women and men. *See* American Lung Association, *Lung Cancer Key Findings* (2022), https://perma.cc/6BJZ-AN87. Screening with annual low-dose CT scans can reduce the lung cancer death rate by up to 20% by detecting tumors at early stages when the cancer is more likely to be curable. *Id.* Lung cancer five-year survival rates are significantly higher when cases are diagnosed at an early stage (61%), compared to when they are not caught until a late stage (7%). *Id.* Early diagnosis rates for lung cancer increased by 33% between 2015 and 2020. *See* American Lung Association, *State of Lung Cancer 2020 Report* at 4, https://perma.cc/T8QU-WFRH. Some estimates indicate that the USPSTF recommendations will reduce lung cancer mortality by an estimated 20% to 33% for high-risk individuals, saving approximately 10,000 to 20,000 additional lives each year. *See* American Society of Clinical Oncology Daily News, *Lung Cancer Screening Remains Poor. Here's How to Increase Rates and Save Lives* (Mar. 20, 2022), https://dailynews.ascopubs.org/do/lung-cancer-screening-remains-poor-here-s-increase-rates-and-save-lives.

15. Statins are yet another example of coverage people could lose with potentially devastating health outcomes. Cardiovascular disease is the leading cause of morbidity and death in the United States. While the USPSTF had earlier recommended screening for people at increased risk for cardiovascular disease, in 2016 USPSTF recommended (and later updated) that clinicians prescribe a statin for the prevention of cardiovascular disease in certain adults with risk factors, as statin use reduces the probability of cardiovascular events, such as heart attacks and strokes. *See* U.S. Preventative Services Task Force, *Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventative Medication* (Aug. 23, 2022), https://perma.cc/82AC-NHYU. Lower copayments for statin medications have been associated with higher levels of adherence, with a $10 increase in copayments resulting in a 1.8 percentage point reduction in the likelihood of adherence for new users and a 3 percentage point reduction in the likelihood of adherence for continuing users. *See* Teresa B. Gibson & Tami L. Mark, *Impact of Statin Copayments on Adherence and Medical Care Utilization and Expenditures*, AMERICAN JOURNAL OF MANAGED CARE (2006), https://perma.cc/MYC8-G4R5. Studies find that poor adherence to statins is associated with increased risks of cardiovascular disease and death. *See* Mary A. De Vera et al., *Impact of Statin Adherence on Cardiovascular Disease and Mortality Outcomes: A Systematic Review*, BRITISH JOURNAL OF CLINICAL PHARMACOLOGY (2014), https://perma.cc/9LMV-M4XT.

16. In addition to the expected losses of coverage, the *Braidwood* decision will also lead to uncertainty in the health insurance market during the pendency of the appeal and will create confusion for a variety of entities, particularly enrollees and providers. For example, enrollees in plans that make mid-year coverage changes may suddenly be billed for services that they thought would be free, creating confusion and significant frustration. Also, providers may

be conflicted if current best practices and standards of care suggest they prescribe preventive services that are now no longer covered.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on April 12, 2022

Jeff Wu
Deputy Director for Policy
Center for Consumer Information & Insurance Oversight (CCIIO)
Centers for Medicare & Medicaid Services (CMS)